NOSB Certification, Accreditation and Compliance Committee 2005 Peer Review Panel Recommendation

Draft 3 – July 8, 2005

Introduction:

The NOSB Certification, Accreditation and Compliance (CAC) Committee has been asked by the NOP to develop a proposal to most effectively implement the "Peer Review Panel" requirements provided for in OFPA and the Final Rule. The following proposal has been prepared taking into account counsel provided to the NOP by the USDA Office of General Counsel (OGC) and the recent audit review of NOP by the American National Standards Institute (ANSI). In order to be implemented, this proposal will require two changes to the Final Rule.

Background:

The Organic Foods Production Act (OFPA) of 1990 contains the following references to peer review:

6516 PEER REVIEW OF CERTIFYING AGENTS.

- (a) Peer Review. In determining whether to approve an application for accreditation submitted under section 6514 of this title, the Secretary shall consider a report concerning such applicant that shall be prepared by a peer review panel established under subsection (b) of this section.
- (b) Peer Review Panel. To assist the Secretary in evaluating applications under section 6514 of this title, the Secretary may establish a panel of not less than three person who have expertise in organic farming and handling methods, to evaluate the State governing official or private person that is seeking accreditation as a certifying agent under such section. Not less than two members of such panel shall be persons who are not employees of the Department of Agriculture or of the applicable State government.

Other than the descriptive text in 6516(b), OFPA does not define "peer review panel." The Final Rule contains the following definition:

"Peer review panel: A panel of individuals who have expertise in organic production and handling methods and certification procedures and who are appointed by the Administrator to assist in evaluating applicants for accreditation as certifying agents."

While current definition of "peer review panel" appears to be consistent with OFPA, it does not match the regulatory text in § 205.509, which states,

"The Administrator shall establish a peer review panel pursuant to the Federal

Advisory Committee Act (FACA) (5 U.S.C. App. 2 et seq.). The peer review panel shall be composed of not less than 3 members who shall annually evaluate the National Organic Program's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the National Organic Program's accreditation decisions. This shall be accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents or documentation. The peer review panel shall report its finding, in writing, to the National Organic Program's Program Manager."

The rule definition states that a peer review panel will "assist in evaluating applicants for accreditation as certifying agents," while the text of 205.509 states that a peer review panel will "evaluate the National Organic Program's adherence to accreditation procedures."

Concerns regarding conflicts of interest and logistics call into question the advisability of forming a panel to evaluate accreditation applicants as described in the definition of "peer review panel." Further, NOP has been advised by OGC that it may not be appropriate for the NOP to be reviewed by individuals they potentially regulate.

Several attempts have been made to instigate a peer review process. In 2001 the NOSB adopted a recommendation to establish a peer review panel (Addendum A). In 2004 the NOP contracted with the American National Standards Institute (ANSI) to evaluate the NOP accreditation program.

The CAC Committee has reviewed the ANSI report and the NOP's response. The ANSI review of NOP is considered by the CAC Committee to be a comprehensive, professional, and independent peer review of the NOP accreditation program for adherence to accreditation procedures of ISO/IEC Guide 61. (Note: The ANSI review did not assess the NOP's adherence to the accreditation procedures in subpart F of the Final Rule or evaluate the NOP's accreditation decisions.)

Recommendation:

In order to implement an ongoing peer review process to evaluate the NOP accreditation program, the Certification, Accreditation and Compliance Committee recommends:

1. The definition of "peer review panel" in 205.2 be changed to read.

"Peer review/auditing organization: An organization, agency or group engaged in accreditation of agencies similar to NOP, with appropriate understanding of accreditation procedures related to organic production and handling methods and

who assist in evaluating the accreditation procedures and policies of the National Organic Program."

2. Section 205.509 of the Final Rule be changed to read:

"The Administrator shall contract with a credible, independent, peer auditing/review organization engaged in accreditation of agencies similar to NOP to conduct a review of NOP accreditation procedures and performance on at least a three-year cycle. The selection of the auditing/review organization will be made by the Administrator with input from NOSB. The scope of the review shall be to evaluate all aspects of the NOP accreditation program including those outlined in subpart F of these regulations and in ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the National Organic Program's accreditation decisions. The NOP will respond to findings within three months of receiving the completed audit report. The review and NOP response will be used as a vehicle for NOP staff and NOSB to jointly develop action plans and priorities in regard to the NOP. The NOSB will review the NOP response and work together with NOP staff to construct a sufficiency assessment and ensure there is constructive discussion and agreement on substantive issues. The audit/review, NOP response, and cooperative review of the audit and response will be used as a vehicle for NOP staff and NOSB to jointly develop action plans and priorities in regard to the NOP."

Conclusion:

By implementing the proposed rule changes, the NOP and NOSB will be able to implement a peer review process that utilizes the expertise of professional auditors and enter into a constructive and collaborative dialogue to develop action plans and priorities to facilitate continuous improvement of the National Organic Program.

Committee vote:

Motion: To accept PRP procedure document as a draft working document. The motion allows for some minor language edits from the author Mike Lacy assisted by Jim Riddle.

Yea - 5

Nea – 0

Absent - 0

Addendum A - NOSB Accreditation Committee Peer Review Panel Recommendation Adopted by the NOSB, June 7, 2001

The Accreditation Committee has been charged with:

- 1) proposing a revised definition of "peer review panel" to bring the definition in line with the Rule's regulatory text;
- 2) drafting an appointment plan with a target of appointment of the PRP by December 31, 2001; and
- 3) drafting terms of reference for operation of the PRP.

1. Peer Review Panel definition. The Federal Rule currently contains the following definition:

<u>"Peer review panel.</u> A panel of individuals who have expertise in organic production and handling methods and certification procedures and who are appointed by the Administrator to assist in evaluating applicants for accreditation as certifying agents."

In order to make the definition consistent with the regulatory text, the Accreditation Committee recommends replacing the current definition with the following:

<u>"Peer review panel.</u> A panel of individuals who have expertise in organic production and handling methods and accreditation procedures and who are appointed by the Administrator to assist in evaluating the accreditation procedures and decisions of the National Organic Program."

2. Peer Review Panel appointment plan.

- A. The Peer Review Panel (PRP) shall be a standing committee of the National Organic Standards Board (NOSB), pursuant to the Federal Advisory Committee Act. (FACA) (5 U.S.C. App. 2 et seq.).
- B. The PRP shall be comprised of 3 members and one alternate. At least one member of the PRP shall be a current NOSB member.
- C. PRP members shall be recommended by the NOSB.
- D. Current NOSB members and members of the public are eligible to serve on the PRP.
- E. PRP members must have expertise in organic production and handling methods and accreditation procedures.
- F. Each member must be recommended for appointment to the PRP by a majority vote of the NOSB. In the event of a plurality, the lowest vote getter must withdraw, and a new ballot is cast.
- G. The Administrator of the USDA's Agricultural Marketing Service shall appoint members of the PRP, based on the recommendations of the NOSB.
- H. Members of the Peer Review Panel may serve up to two 3-year terms.
- I. In order to establish an appointment rotation cycle, members of the first Peer Review

Panel shall be appointed to 1-, 2-, and 3-year terms, with the alternate member appointed to a 3-year term.

3. Peer Review Panel terms of reference.

The Federal Rule contains the following regulatory text establishing the duties of the Peer Review Panel:

"§ 205.509 Peer review panel.

The Administrator shall establish a peer review panel pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 et seq.). The peer review panel shall be composed of not less than 3 members who shall annually evaluate the National Organic Program's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the National Organic Program's accreditation decisions. This shall be accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents or documentation. The peer review panel shall report its finding, in writing, to the National Organic Program's Program Manager."

The Accreditation Committee recommends that the Peer Review Panel operate according to the following terms of reference:

- A. The Peer Review Panel shall annually evaluate the National Organic Program's adherence to the accreditation procedures in subpart F of the Federal Rule.
- B. The PRP shall annually evaluate the National Organic Program's adherence to ISO/IEC Guide 61, *General Requirements for Assessment and Accreditation of Certification/Registration Bodies*.
- C. The PRP shall annually evaluate the National Organic Program's accreditation decisions for compliance with the Act, the Federal Rule, and ISO/IEC Guide 61.
- D. The PRP shall annually review the NOP's accreditation procedures, document reviews, and site evaluation reports.
- E. The PRP shall annually review the NOP's accreditation decision documents and/or documentation.
- F. The PRP shall report its findings, in writing, to the National Organic Standards Board and to the National Organic Program's Program Manager.
- G. The report shall be constructed as a consensus document of the PRP, but it may contain minority findings or positions.
- H. The proceedings of the PRP shall be confidential, but the findings shall be contained in a publicly available document.
- I. PRP members shall recuse themselves from review of NOP accreditation decisions concerning certifying agents with whom they or members of their immediate families have conflicts of interest.
- J. Upon appointment, PRP members shall receive auditor training in ISO/IEC Guide 61 and ISO/IEC Guide 10011.

- K. The PRP shall travel to the USDA offices at least annually to conduct reviews of the NOP's accreditation program. PRP members may also accompany representatives of the NOP during site evaluations of certifying agents.
- L. The PRP will be provided sufficient staff support and resources by the NOP to carry out the duties described in A–K above.